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AMENDED APPEAL BRIEF

Applicant	:	Kagan et al.
App. No	:	10/698,148
Filed	:	October 31, 2003
For	:	APPARATUS AND METHODS FOR TREATMENT OF MORBID OBESITY
Examiner	:	Phillip A. Gray
Art Unit	:	3767

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/Bryan Wahl/
Bryan Wahl, Reg. No. 58,878

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Dear Sir:

In accordance with the Notice of Appeal filed on January 11, 2010, and further in response to the Office Communication of August 25, 2010, Appellants submit this Amended Appeal Brief including the noted appendices.

Appellants submit that this Amended Appeal Brief is in compliance with 37 C.F.R. § 41.37 and includes a mapping of the independent claim to the paragraph number of the specification as filed. Appellants submit this Appeal Brief including the noted appendices.

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I. REAL PARTY IN INTEREST

The real party in interest is ValenTx, Inc., which is the assignee of the above-identified patent application.

II. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

III. STATUS OF CLAIMS

Claims 43-50, 52, 54-61, and 72-73 are currently pending. Claims 1-42, 51, and 53 have been cancelled. Claims 62-71 and 74-75 are withdrawn. Claims 43-50, 52, 54-61, and 72-73 stand rejected, and are the subject of this Appeal. Claim 43 is the sole pending independent claim. The claims that are subject to appeal are attached hereto as Appendix A.

IV. STATUS OF AMENDMENTS

The claims before the Board appear as they were submitted in the Response dated November 21, 2008 and acknowledged as entered in the Office Action mailed February 19, 2009. No further amendments have been made to the claims. The appealed claims are attached hereto as Appendix A.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In general, the current claims are directed to a method of treating a patient (who may be obese). The steps of the method include providing a gastrointestinal sleeve, having a proximal end, a distal end, and a lumen extending therethrough; transesophageally advancing the sleeve to position the proximal end adjacent an attachment site near the gastroesophageal junction; advancing the distal end through the stomach and into the intestine; and attaching the proximal end at the attachment site without creating a serosal to serosal bond (to promote a secure yet reversible attachment), such that the sleeve is configured to deliver food from the esophagus

directly into the intestine; wherein the attaching the proximal end step comprises anchoring at least one tissue anchor having a proximal end and a distal end, said anchoring comprising changing the distal end of the tissue anchor from a transversely reduced configuration used while passing transmurally through the attachment site to a transversely enlarged configuration used after passing transmurally through the attachment site, wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface to retain the sleeve, and wherein the enlarged configuration of the tissue anchor is transversely larger than any transverse portion of the tissue anchor when the tissue anchor is passing transmurally through the attachment site in the reduced configuration.

One illustrative non-limiting example of a gastrointestinal sleeve positioned after the transesophageally advancing the sleeve to position the proximal end adjacent an attachment site near the gastroesophageal junction and advancing the distal end through the stomach and into the intestine steps is illustrated in Fig. 23B of the present application, reproduced below:

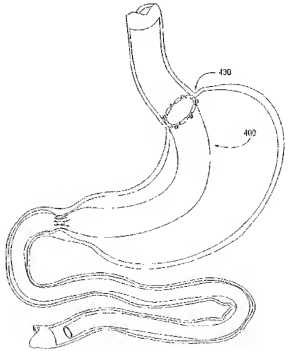

FIG 23B

One example of the tissue anchor in its transversely enlarged configuration, in which the distal end of the tissue anchor including a proximally facing surface which rests against a serosal surface to retain the sleeve is illustrated in Fig. 46B of the present application, which is reproduced below:

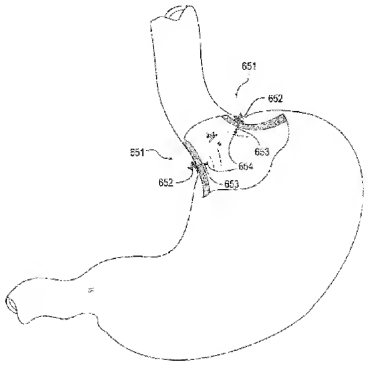

FIG 46B

Independent Claim 43 is argued in the present appeal and is reproduced below. Some non-limiting examples of written description support for the elements in independent Claim 43 is indicated (paragraph and/or Figure numbers **in bold**). Each of the elements of the independent claim at issue in the appeal is discussed in more detail below, with non-limiting examples of appropriate reference numbers listed, and paragraph numbers referring to the application as originally filed.

Claim 43 recites:

A method of treating a patient, comprising the steps of:

providing a gastrointestinal sleeve (400), having a proximal end (402), a distal end, and a lumen extending therethrough; **(Figs. 15, 16)**

transesophageally advancing the sleeve (400) to position the proximal end (402) adjacent an attachment site near the gastroesophageal junction; **[0269]**

advancing the distal end through the stomach and into the intestine; and **[0251]**

attaching the proximal end (402) at the attachment site without creating a serosal to serosal bond, such that the sleeve (400) is configured to deliver food from the esophagus directly into the intestine; **(Figs. 15, 16, 46B)**

wherein the attaching the proximal end step comprises anchoring at least one tissue anchor (651) having a proximal end (654) and a distal end (652), said anchoring comprising changing the distal end (652) of the tissue anchor (651) from a transversely reduced configuration used while passing transmurally through the attachment site to a transversely enlarged configuration used after passing transmurally through the attachment site, wherein the distal end (652) of the tissue anchor (651) includes a proximally facing surface (652) which rests against a serosal surface to retain the sleeve (400), and wherein the enlarged configuration of the tissue anchor (651) is transversely larger than any transverse portion of the tissue anchor (651) when the tissue anchor (651) is passing transmurally through the attachment site in the reduced configuration. **[0360], [0361], (Fig. 46B)**

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 43-50, 52, 54-61, and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pub. No. 2004/0039452 A1 to Bessler in view of U.S. Pat. No. 6,254,642 to Taylor, and further in view of U.S. Pat. No. 5,470,337 to Moss. The aforementioned claims also stand rejected in view of U.S. Pub. No. 2004/0082963 A1 to Gannoe et al. in view of Taylor, and

further in view of Moss. Claim 52 is also rejected as unpatentable over Bessler in view of Taylor in further view of Moss or Gannoe in view of Taylor in further view of Moss.

VII. ARGUMENT

A. Legal Requirements for Establishing a *prima facie* Showing of Obviousness

The Examiner bears the initial burden to establish and support a *prima facie* case of obviousness.[1] To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art.[2] The Court, in *KSR International v. Teleflex* has made it clear that there should be some reason, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify or combine the elements to achieve the claimed combination.[3] A *prima facie* case of obviousness can only be established if there is a reasonable expectation of success in the combination.[4] Furthermore, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.[5]

Secondary considerations, including unexpected results, long-felt need, and failure of others, can rebut a *prima facie* case of obviousness because that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.[6]

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[1] See *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (C.C.P.A. 1976).
[2] See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974).
[3] See *KSR International v. Teleflex*, 550 U.S. 398, 418 (2007) ("'[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'" *quoting In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).
[4] M.P.E.P. § 2143.02.
[5] *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); M.P.E.P. § 2142.01 (VI).
[6] *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

B. Claims 43-50, 52, 54-61 and 72-73 Would Not have been Obvious over Bessler in view of Taylor, and further in view of Moss.

In the Final Office Action, the Examiner asserted that Claims 43-50, 52, 54-61, and 72-73 are unpatentable under 35 U.S.C. § 103 over Bessler in view of Taylor and Moss as noted in Section VI above.

Appellants submit that the Examiner has failed to establish a *prima facie* case of obviousness. "The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious... [R]ejections on obviousness cannot be sustained with mere conclusory statements."[7]

1. One of Ordinary Skill Would Have No Reason to Combine the References

In *KSR*, the Court repeatedly emphasized the value of determining if there is any "reason to combine" the various teachings in the art. The Court noted that "[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art."[8] Thus, the Court has made it abundantly clear that some reason to combine the various elements must be present in order to establish a *prima facie* case of obviousness. Furthermore, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.[9]

Bessler discloses a gastric bypass "stent" 2 comprising a stent member 4 at the proximal end 6 of a tubular member 8.[10] An optional second stent 10 may be provided at the distal end of the tubular member 8.[11] Every embodiment in Bessler discloses a nonpuncturing attachment system, in the form of one or more self expandable or balloon expandable stents.

[7] M.P.E.P. § 2142.
[8] *KSR*, 550 U.S. at 418.
[9] *See W.L. Gore*, 721 F. 2d at 1550; M.P.E.P. § 2142.01 (VI).
[10] Bessler at para. [0018].
[11] *Id.*

In the course of distinguishing the prior art, Bessler at ¶ [0005] explained: "There has been, and continues to be, a need for less traumatic surgical or non-surgical techniques to treat obesity." Bessler's exclusive use of nonpuncturing fixation was therefore a well-considered aspect of his design. By the time of Bessler's filing date, persons of ordinary skill in the medical device arts were familiar with a wide variety of invasive tissue engaging attachment structures such as staples, sutures, and barbs.[12] Yet Bessler failed to disclose even a single puncturing attachment structure, signaling in the context of Bessler's disclosure a clear preference for nonpuncturing attachment.

Taylor fails to cure the deficiency in the teachings of Bessler. Unrelated to obesity, Taylor teaches the implantation of a valve to treat gastroesophageal reflux disease. Referring to Figures 6A-6E, referenced by the Examiner, a plurality of fixed barbed spikes 25 are driven through adjacent tissue. The use of sharpened barbs as disclosed in Taylor are therefore inconsistent with Bessler's apparent intent of providing a non-penetrating less traumatic device for gastric bypass. Thus, even disregarding the different intended use of treating GERD, the addition of an invasive attachment structure in the context of Bessler fails to establish a *prima facie* case.

Even assuming the combination of the barbed spikes of Taylor with the bypass structure of Bessler were a proper combination, it would still fail to yield a *prima facie* showing of obviousness. This is because the barbs disclosed in Taylor clearly fail to disclose the presently claimed feature by which the distal end of the tissue anchor changes from a transversely reduced configuration used while passing transmurally through the attachment site to a transversely enlarged configuration used after passing transmurally through the attachment site, as recited in Claim 43.

Recognizing this deficiency, the Examiner has relied upon a further combination with Moss. Moss is representative of a class of surgical fasteners often referred to as "T-tags" and discloses such fasteners in either a "I" or "H" shape. A person of ordinary skill in the art

[12] *See, e.g.,* Taylor at col. 1, lines 61-63; col. 3 line 47 – col. 4 line 13; col. 4 lines 38-46.

attempting to practice the invention of Bessler would have no reason to include a penetrating fastener of the type disclosed in Moss any more than a penetrating fastener of the type disclosed in Taylor. Appellants respectfully submit that one of skill in the art would have absolutely no reason to add the penetrating attachment anchors of Moss which are movable from a reduced cross section to an enlarged cross section to the disclosure of Bessler.[13]

Furthermore, Appellants submit that the Examiner must consider Bessler in its entirety including its particular non-penetrating anchoring system that leads away from the claimed invention.[14] As such, when attempting to make a combination, the Examiner cannot merely pick out the tubular member of Bessler and ignore the non-penetrating manner in which the Bessler tubular member is attached. Combining Bessler's tubular member with the penetrating attachment mechanisms taught in Taylor and further modified by Moss to come up with the invention as claimed is wholly improper.[15] Thus, Appellants submit that the Examiner has failed to provide a cognizable reason to combine the references.

2. One of Ordinary Skill Would Have No Reasonable Expectation of Success in the Combination

Furthermore, a *prima facie* case of obviousness can only be established if there is a reasonable expectation of success in the combination.[16] As noted in multiple response of record and the Thompson Declaration, prior to the present invention, to Appellants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction with the exception perhaps of esophageal stents in certain cancer patients, have generally resulted in failure.[17] The Examiner has failed to provide evidence of a reasonable expectation of success in

[13] 37 C.F.R. § 1.132 Declaration of Christopher Thompson, M.D. filed on November 21, 2008 at para. 9 (hereinafter "Thompson Declaration").
[14] *See W.L. Gore*, 721 F.2d at 1550; M.P.E.P. § 2142.01 (VI).
[15] *See id.*
[16] M.P.E.P. § 2143.02.
[17] *See* Thompson Declaration at para. 9.

the cited combination, and furthermore has failed to rebut or even acknowledge in any Office Action the substantial evidence provided by Appellants that no reasonable expectation of success exists. For at least the foregoing reasons, no reasonable expectation of success in the combination exists. *See also* the discussion of failure of others at Section 3(b), *infra.*

3. Secondary Considerations Support a Finding of Non-Obviousness

Secondary considerations must be considered in every case where they are presented.[18] These include factors such as unexpected results, long-felt need, and failure of others.[19] A *prima facie* case of obviousness can also be rebutted if the applicant can show that the art in any material respect taught away from the claimed invention.[20]

a. Teaching Away

Bessler discloses that his device is advantageous as less traumatic than previous surgical techniques.[21] All disclosed embodiments of Bessler's device, involve an expandable stent 4[22] that does not penetrate any tissue walls to meet its objective of securing the ends of the device within the esophagus. In general, the teachings of Bessler would lead one of skill in the art in the direction of a non-penetrating anchoring system, such as a balloon expandable or self expanding stent as disclosed therein. Thus, Appellants submit that Bessler tends to teach away from the use of a penetrating tissue attachment, and that the use of Taylor or Moss's penetrating tissue fastener

[18] *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); *KSR*, 550 U.S. at 399.
[19] *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); *Graham v. John Deere*, 383 U.S. 1 (1966); *In re Sullivan*, 498 F.3d 1345, 1351 (Fed. Cir. 2007)(holding the PTO is obligated to consider applicant evidence of secondary consideration in cases where obviousness is at issue).
[20] *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001).
[21] Bessler at paragraph [0005].
[22] *Id.* at Fig. 1.

to secure Bessler's bypass stent would be contrary to Bessler's intent of providing a less traumatic device for gastric bypass.[23]

b. Failure of Others/Unexpected Results

Prior to the present invention, to Appellants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction in absence of esophageal cancer have generally resulted in failure. These methods have experienced a myriad of problems such as, for example, anchor migration, wall erosion, or rupture resulting in undesired device placement or explantation. Investigators have tried for years, without success, to achieve stable attachment of a variety of devices in the gastroesophageal junction region.[24] The patent literature reflects numerous concepts involving the implantation of a device in or near the stomach to treat obesity. Yet none appear to have achieved clinical success. It is well known that obesity has been cited as a contributing factor to countless deaths in the United States per year and has increased health care use and expenditures, costing society tremendous resources that are both direct (preventive, diagnostic, and treatment services related to weight) and indirect (absenteeism, loss of future earnings due to premature death) costs.

Indeed, the assignee of the present application has expended a considerable amount of time, effort and money in its attempts to achieve a safe, stable fixation in the vicinity of the gastroesophageal junction. The stomach's response to the presence of implants is highly unpredictable, and it was completely unexpected that Appellants' claimed method using a transmural attachment having a transverse surface for contacting the serosa and which is transformable from a reduced configuration for transmural passage to an enlarged configuration for placing a footprint against the serosal surface would achieve stable fixation. Both animal and human trials performed thus far have shown the present claimed invention to be very effective in stably and securely attaching a bypass sleeve or attachment cuff to an attachment site near the

[23] *See* Thompson Declaration at para. 7.

gastroesophageal junction.[25] The success of Appellants' claimed methods and devices could not have been predicted from any of the teachings of Bessler, Taylor or Moss raised by the Examiner as a basis of rejection.

C. Claims 43-50, 52, 54-61 and 72-73 Would Not have been Obvious over Gannoe in view of Taylor, and further in view of Moss.

1. One of Ordinary Skill Would Have No Reason to Combine the References

Gannoe discloses methods and devices for creating a tissue ring such as in the upper stomach. As shown in Fig. 5E of Gannoe, use of the disclosed device results in acquiring tissue folds in a circumferential configuration within a hollow body organ (Abstract) with mucosal tissue on both external surfaces of the placation, and serosal tissue "sandwiched" in between the mucosal layers. This results in each end of the staple being attached to a mucosal surface of tissue. Attachment of a bypass conduit 113 at the GEJ at the tissue ring, as shown in Fig. 5E of Gannoe, results in each end of the staple resting against mucosal tissue of a circumferential tissue fold. Gannoe acknowledges the unsolved problem of how to attach a device in the stomach, and proposes as a solution bringing the two external serosal surfaces in contact with each other across a tissue fold. This results in a permanent serosa to serosa scar tissue bond to reinforce and hold a tissue plication in place. Because, among other things, the serosa to serosa bond is permanent without surgical or other invasive intervention, Appellants specifically avoid this approach and have expressly excluded this from the present claims. As noted above, Appellants submit that the Examiner must consider the primary reference cited as the basis for the rejection, Gannoe, in its entirety, including its particular plication anchoring system that leads away from the claimed

[24] *Id.* at para. 9.
[25] *Id.*

invention.[26] As such, when attempting to make a combination, the Examiner cannot merely pick out Gannoe's sleeve while ignoring the permanently tissue altering plication anchoring system. It would be wholly improper to combine Gannoe's sleeve with the particular attachment mechanisms taught in Taylor and further modified by Moss to come up with the invention as claimed.[27] Thus, Appellants submit that the Examiner has failed to provide a cognizable reason to combine the references.

2. References, Even When Combined, Fail to Disclose the Invention as Claimed

Even assuming for the sake of argument that Gannoe, Taylor, and Moss are combinable, a combination of Gannoe, Taylor, and Moss would result in a gastric bypass stent wherein a penetrating attachment is driven through a mucosal-to-mucosal plication as taught by Gannoe. Such a combination will still facilitate serosal to serosal bonding via the plication, contrary to the recitation of Claim 43 of "attaching the proximal end [of the gastrointestinal sleeve] at the attachment site without creating a serosal to serosal bond." Side-by-side illustrations of the serosal-to-serosal bond created by Gannoe and an embodiment of the attachment without creating a serosal to serosal bond claimed by Appellants are depicted on the next page. The Examiner has simply failed to identify how the proposed combination would create an attachment without creating a serosal to serosal bond as claimed. Since the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a *prima facie* case of obviousness. Furthermore, further modifying the combination (i.e., removing Gannoe's serosal to serosal bond for attachment) would destroy the purpose of Gannoe's device and act as a substantial disincentive for the proposed combination.[28]

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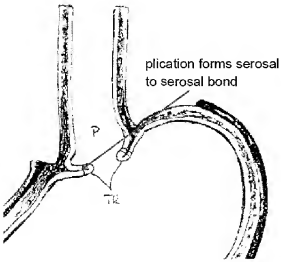
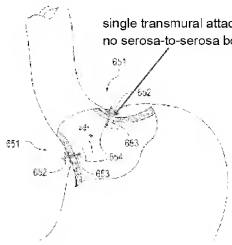
[26] *W.L. Gore*, 721 F.2d at 1550; M.P.E.P. § 2142.01 (VI).
[27] *See id.*

[28] *See* M.P.E.P. § 2143.01(V).



Gannoe



Embodiment of claimed method

3. Secondary Factors Support A Finding of Non-Obviousness

a. Teaching Away

As noted above, Gannoe teaches a mucosal to mucosal puncture of a plication, for the purpose of both reducing the diameter of the opening at the base of the esophagus and to permit serosa to serosa bonding to enable a lasting clinical result. This disclosure would not give one of ordinary skill in the art any reason to eliminate the plication which is of central importance to Gannoe and accordingly contained in every embodiment disclosed in Gannoe. As noted above, the Examiner must take into account the Gannoe reference as a whole, and it is not permissible to conveniently ignore the plication feature when attempting to combine references.[29] Gannoe's objective of obtaining permanent serosa to serosa healing thus at least implicitly teaches away from the invention as claimed, which excludes serosa to serosa bonding as recited in Claim 43.[30] In general, the teachings of Gannoe would lead one of skill in the art in the direction of creating a

[29] *See W.L. Gore*, 721 F.2d at 1550.
[30] *See* Thompson Declaration at para. 8.

plication for serosal-to-serosal bonding for permanent healing. Thus, Appellants submit that Gannoe tends to teach away from the use of Appellants' claimed transmural tissue attachment, which pursues the opposite objective of achieving attachment while leaving the native anatomy intact. Furthermore the use of Taylor's spikes through a non-plicated tissue wall to secure Gannoe's sleeve device would be contrary to Gannoe's intent of providing a plication for permanent serosa-to-serosa bonding. *See id.*

b. Failure of Others/Unexpected Results

As noted above, prior to the present invention, to Appellants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction with the exception perhaps of esophageal stents in certain cancer patients, have generally resulted in failure.[31] These methods have experienced a myriad of problems such as, for example, anchor migration, wall erosion, or rupture resulting in undesired device placement or explantation.[32] Appellants submit that one of ordinary skill in the art would be concerned that attempts to modify such devices would render them difficult or dangerous to remove from the gastrointestinal tract, and in fact it was unexpected that the claimed methods have been very effective in stably and securely attaching a device to an attachment site near the gastroesophageal junction, as evidenced by both animal and human trials performed thus far.[33]

In short, Appellants' surprising success in achieving attachment without substantial modification to the native tissue in the vicinity of the gastroesophageal junction was completely unpredictable to those of skill in the art familiar with the prior art references applied herein. However, even assuming arguendo that the Examiner has established a prima facie case of obviousness, secondary factors, including unexpected results, failure of others, and long felt need, necessitate a finding of nonobviousness.

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[31] *See id.* at para. 9.
[32] *Id.*
[33] *Id.*

D. Claim 52 Would Not have been Obvious over Bessler in view of Taylor in further view of Moss, or Gannoe in view of Taylor, and further in view of Moss.

Appellants reiterate all of the arguments stated above with respect to Claim 43, and note that Claim 52 depends from Claim 43 and recites all of the elements thereof in addition to further distinguishing features. As such, Appellants respectfully request that the rejection of Claim 52 be reversed.

E. The Examiner Must Give Proper Weight to the Thompson Declaration

The Examiner has expressed during the telephone interview of February 12, 2010 and the Examiner's Interview Summary mailed on February 24, 2010 that the Thompson Declaration of record was not entitled to sufficient weight as mere "opinion evidence," Appellants disagree. The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.[34] The Examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, etc.[35] Opinions introduced on the issue of the level of ordinary skill are usually determined by reference to the subjective reaction of persons so skilled, and even assuming for the sake of argument that a *prima facie* case of obviousness has been established, opinion evidence of one of ordinary skill in the art based on information uniquely within their competence bearing on the level of ordinary skill in the art at the time the invention was made can overcome a *prima facie* case of obviousness.[36]

Similar to the *Oelrich* and *Meng* cases cited above, in which opinion affidavits of one of ordinary skill in the art regarding the level of skill in the art was considered dispositive in finding

[34] M.P.E.P. § 2143.01 (III), *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991).
[35] *See* M.P.E.P. § 2143.01 (III), *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693 (Fed. Cir. 1983), *cert denied*, 464 U.S. 1043 (1984).
[36] *In re Oelrich*, 579 F.2d 86, 91 (C.C.P.A. 1978); *In re Meng*, 492 F.2d 843, 848-849 (C.C.P.A. 1974)

that a claimed invention was nonobvious, the Thompson Declaration was also introduced on the issue of the level of ordinary skill, and as such should be entitled to considerable weight. Dr. Thompson was a physician in the art at the time the invention was made who has substantial clinical and research experience in gastrointestinal procedures that are the subject of the claimed invention.[37] The Thompson Declaration opines on the art cited as a basis for an obviousness rejection by the Examiner based on Dr. Thompson's knowledge, clinical, and research experience that is uniquely within his competence, and clearly states reasons why he would see no reason to combine the cited references to come up with the claimed invention, why he would not have expected the invention to have a reasonable expectation of success, and how the claimed invention produced unexpected results.[38] As such, Appellants submit that the Thompson Declaration is compelling evidence of nonobviousness of record on the issue of the level of ordinary skill.[39] Thus, Appellants respectfully request that the Board consider the Declaration, and afford it considerable weight in view of the relevant case law and M.P.E.P. sections cited above.

VIII. CONCLUSION

In summary, the references cannot be reasonably combined because the prior art does not provide any reason to make the cited combination, especially when the prior art references are properly considered as a whole, including portions that may teach away from the invention as claimed. Furthermore, the references do not provide a reasonable expectation of success in such a combination. As a result, the Examiner has not made a prima facie case of obviousness. However, even assuming arguendo that the Examiner has established a prima facie case of obviousness, secondary factors, including unexpected results and long felt need, necessitate a finding of nonobviousness. In addition, while independent Claim 43 is being specifically argued in the present appeal, Appellants note that dependent Claims 44-50, 52, 54-61, 72-73, as well as

[37] Thompson Declaration at paras. 1-3.
[38] *Id.* at paras. 7-9.
[39] *See* M.P.E.P. § 2143.01 (III); *Oelrich*, 579 F.2d at 91; *Meng*, 492 F.2d at 848-849.

withdrawn claims 62-71 and 74-75 incorporate all the elements of the independent claims. Therefore these dependent and withdrawn claims are nonobvious for at least the reasons discussed above, and Appellants request that the withdrawn claims be reinstated into the application should Claim 43 be found allowable.

Co-Pending Applications of Assignee

Appellants wish to draw the Board's attention to the following co-pending applications of the present application's assignee, which are of record in previous Information Disclosure Statements.

Serial Number	Title	Filed
10/998,424	Apparatus and Methods for Treatment of Morbid Obesity	11/29/2004
11/025,364	Devices and Methods for Treating Morbid Obesity	12/29/2004
11/124,634	Devices and Methods for Attachment of an Endolumenal Gastrointestinal Implant	05/05/2005
11/431,040	Methods of Transmural Attachment in the Gastrointestinal System	05/09/2006
11/430,677	Attachment System for Transmural Attachment at the Gastroesophageal Junction	05/09/2006
11/431,054	Methods of Adjusting Therapy in a Patient Having an Endolumenal Bypass to Treat Obesity	05/09/2006
11/400,724	Devices and Methods for Endolumenal Gastrointestinal Bypass	04/07/2006
11/430,275	Everting Gastrointestinal Sleeve	05/08/2006
11/430,278	Attachment Cuff for Gastrointestinal Implant	05/08/2006
11/430,274	Cuff and Sleeve System for Gastrointestinal Bypass	05/08/2006
11/429,934	Gastrointestinal Implant System	05/08/2006
11/548,605	Devices and Methods for Endolumenal Gastrointestinal Bypass	10/11/2006
10/903,255	Gastrointestinal Sleeve Device and Methods for Treatment of Morbid Obesity;	07/30/2004
11/236,212	Devices and Methods for Attachment of a Gastrointestinal Sleeve	09/27/2005
11/123,889	Devices and Methods for Gastric Surgery	05/06/2005

Serial Number	Title	Filed
11/125,820	Suction Assisted Tissue Plication Device and Method of Use	05/10/2005
11/789,561	Methods and Devices for Gastrointestinal Stimulation	04/25/2007
11/861,156	Toposcopic Access and Delivery Devices	09/25/2007
11/861,187	Toposcopic Methods and Devices for Delivering an Elongate Sleeve Having Axially Compressed and Elongate Configurations	09/25/2007
11/861,172	Methods for Toposcopic Sleeve Delivery	09/25/2007
12/136,003	Methods and Devices for Intragastric Support of Functional or Prosthetic Gastrointestinal Devices	06/09/2008
12/135,989	Gastrointestinal Bypass Sleeve as an Adjunct to Bariatric Surgery	06/09/2008
12/137,473	Expandable Fastener System with Flower Petal-Shaped Retention Elements	06/11/2008
12/137,475	Endoscopic Delivery Devices and Methods	06/11/2008

IX. SUMMARY OF CLAIMS APPENDIX

Attached hereto as Appendix A is a copy of the claims presented for appeal.

X. SUMMARY OF EVIDENCE APPENDIX

Attached hereto as Appendix B is a copy of:

1. 37 C.F.R. § 1.132 Declaration of Christopher Thompson, M.D. submitted November 21, 2008.

XI. SUMMARY OF RELATED PROCEEDINGS APPENDIX

No related appeal proceedings are known.

For at least the foregoing reasons, Appellants submit that all of the pending claims are allowable, and respectfully request that the Board find the same. Please charge any additional

fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 26, 2010

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APPENDIX A
CLAIMS PRESENTED FOR APPEAL

43. A method of treating a patient, comprising the steps of:

providing a gastrointestinal sleeve, having a proximal end, a distal end, and a lumen extending therethrough;

transesophageally advancing the sleeve to position the proximal end adjacent an attachment site near the gastroesophageal junction;

advancing the distal end through the stomach and into the intestine; and

attaching the proximal end at the attachment site without creating a serosal to serosal bond, such that the sleeve is configured to deliver food from the esophagus directly into the intestine;

wherein the attaching the proximal end step comprises anchoring at least one tissue anchor having a proximal end and a distal end, said anchoring comprising changing the distal end of the tissue anchor from a transversely reduced configuration used while passing transmurally through the attachment site to a transversely enlarged configuration used after passing transmurally through the attachment site, wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface to retain the sleeve, and wherein the enlarged configuration of the tissue anchor is transversely larger than any transverse portion of the tissue anchor when the tissue anchor is passing transmurally through the attachment site in the reduced configuration.

44. A method of treating a patient as in Claim 43, further comprising the additional step of implanting a support at the site, for linking the proximal end of the sleeve to the site.

45. A method of treating a patient as in Claim 44, wherein the support is implanted in the same procedure as the sleeve.

46. A method of treating a patient as in Claim 44, wherein the support is implanted in a first procedure and the sleeve is attached to the support in a second procedure.

47. A method of treating a patient as in Claim 43, wherein the advancing the distal end step comprises advancing the distal end at least as far as the ligament of Treitz.

48. A method of treating a patient as in Claim 43, wherein the advancing the distal end step comprises advancing the distal end distally of the duodenum.

49. A method of treating a patient as in Claim 43, wherein the advancing the distal end step comprises advancing the distal end into the jejunum.

50. A method of treating a patient as in Claim 43, wherein the attaching the proximal end step comprises using a suture.

52. A method of treating a patient as in Claim 43, wherein the tissue anchor comprises a "T" tag.

54. A method of treating a patient as in Claim 44, wherein the support comprises a tubular cuff.

55. A method of treating a patient as in Claim 54, comprising attaching the cuff at the site with at least one transmural anchor.

56 A method of treating a patient as in Claim 43, wherein the sleeve is at least about 50 cm in length.

57. A method of treating a patient as in Claim 43, wherein the sleeve is at least about 75 cm in length.

58. A method of treating a patient as in Claim 43, wherein the sleeve is at least about 125 cm in length.

59. A method of treating a patient as in Claim 56, wherein the sleeve is sufficiently flexible that material traveling through the sleeve is influenced by the natural operation of the pylorus.

60. A method of treating a patient as in Claim 54, wherein the sleeve is removably attached to the cuff.

61. A method of treating a patient as in Claim 54, wherein the sleeve is permanently attached to the cuff.

72. A method of treating a patient as in Claim 43, wherein the transversely enlarged configuration is achieved by expanding the anchor after passing through the serosal tissue.

73. A method of treating a patient as in Claim 43, wherein the transversely enlarged configuration is achieved by flexing a portion of the anchor after passing through the serosal tissue.

APPENDIX B
EVIDENCE

1. 37 C.F.R. § 1.132 Declaration of Christopher Thompson, M.D. submitted November 21, 2008.

APPENDIX C

RELATED PROCEEDINGS

No related appeal proceedings are known.

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